TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		CUSTOMER NO. 22,852 ATTORNEY'S DOCKET NUMBER 07580.0008
		U.S. APPLICATION NO. **10/553,798**
INTERNATIONAL APPLICATION NO. PCT/JP2004/005444	INTERNATIONAL FILING DATE April 16, 2004	PRIORITY DATE CLAIMED April 18, 2003

TITLE OF INVENTION
AGENT FOR INCREASING GRANULOCYTE MACROPHAGE COLONY STIMULATING FACTOR

APPLICANT(S) FOR DO/EO/US
Satoshi YOSHIDA and Takahisa USHIROYAMA

Applicant(s) herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c)(2)).
   - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   - b. ☐ has been communicated by the International Bureau.
   - c. ☐ is not required, as the application was filed with the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   - a. ☐ is attached hereto.
   - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)).
   - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   - b. ☐ have been communicated by the International Bureau.
   - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ Information Disclosure Statement under 37 CFR 1.97 and 1.98
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A Substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.2 and 35 U.S.C. 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154 (d)(4).
19. ☐ A second copy of the English language translation of the international application 35 U.S.C. 154 (d)(4).
20. ☒ Other items or information:
    - a. ☒ Copies of seven references cited on PTO/SB/08
    - b. ☐
    - c. ☐
    - d. ☐
    - e. ☐
    - f. ☐
    - g. ☐

U.S. APPLICATION NO.) **10/553,798**	INTERNATIONAL APPLICATION NO. PCT/JP2004/005444	**ATTORNEY'S DOCKET NUMBER** 07580.0008

The following fees have been submitted:	**CALCULATIONS**	**PTO Use Only**
21. ☐ BASIC NATIONAL FEE (37 CFR 1.492(a)): **$300.00**		
22. ☐ Examination fee (37CFR 1.492(c)) If the Written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... **$0** All other situations **$200**		
23. ☐ Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... **$0** Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... **$100** International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... **$400** All other situations **$500**		
TOTAL of 21, 22 and 23 =		
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is **$250** for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	Rate		
20 - 100 =	/50=		x $250.00	$	
Surcharge of **$130.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	1 - 20 =		x $50.00	$	
Independent Claims	1 -3 =		x $200.00	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+$360.00	$	
			TOTAL OF ABOVE CALCULATIONS =		
☐ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.				$	
			SUBTOTAL =		
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest priority date (37 CFR 1.492(i)). +				$	
			TOTAL NATIONAL FEE =		
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property. +					
			TOTAL FEES ENCLOSED =		
				Amount to be refunded:	$
				charged:	$

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☐ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING**: Information on this form may become public. **Credit card information should not be included on this form**. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

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NAME/REGISTRATION NUMBER

DATED: January 30, 2006

PATENT
Customer No. 22,852
Attorney Docket No. 7580.0008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Satoshi Yoshida et al.	)	Group Art Unit: 1654
	)	
Application No.: 10/553,798	)	Examiner: Unassigned
	)	
Filed: October 18, 2005	)	
	)	
For: AGENT FOR INCREASING GRANULOCYTE MACROPHAGE COLONY STIMULATING FACTOR	)	Confirmation No.: Unassigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents on the attached listing. To the undersigned's knowledge, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for this application. Copies of the non-patent literature documents are attached. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

For the documents listed on the attached PTO/SB/08 that are not in the English language, the specification provides the following concise statements of relevance:

1. On page 1, beginning at line 26, the specification cites THE MERCK MANUAL for its teaching that the two cytokines granulocyte colony stimulating factor (G-CSF) and GM-CSF stimulate the proliferation of the granulocyte progenitor fraction, and that those cytokines are in use as first-line drugs for leucopenia and granulopenia.

2. Page 1, lines 20-26 of the specification, cites the MIZOGUCHI article for its teaching of diseases associated with a low level of GM-CSF in the blood, including neutropenia, aplastic anemia, osteomyelodysplasia syndrome, and that GM-CSF is used for the treatment of those diseases.

3. Page 2, lines 8-12 of the specification, cites the TAKEUCHI article for its teaching that TNF bonds with receptors present in almost all cells within an organism and thereby exhibits extensive actions. In addition, the specification on page 3, lines 13-16, cites this references for its teaching that TNF is closely connected to the excess production of the cytokines IL-1 and IL-6 and has an important role in rheumatoid arthritis (RA).

4. Beginning on page 17, line 22, the specification discusses the teaching of URABE that the undesirable symptoms associated with the administration of GM-CSF include fever.

5. On page 2, lines 28, the specification cites the WATANABE reference for its teaching that, in Crohn's disease, the average TNF-α of four patients in the inactive period is 11.98 pg/ml and the average TNF-α of four patients in active period is 404.76 pg/ml.

6. The specification on page 2, lines 17-22, cites the YAMAMURA reference for its teaching that, in patients with rheumatoid arthritis, TNF-α reaches 15.0 ± 9.2 pg/ml.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

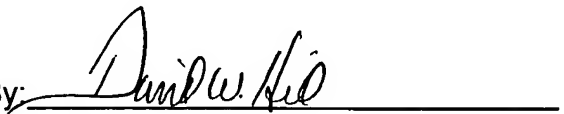
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 30, 2006

By: 
David W. Hill
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IDS Form PTO/SB/08: Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1

Complete if Known	
Application Number	10/553,798
Filing Date	October 18, 2005
First Named Inventor	Satoshi Yoshida et al.
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	7580.008

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-4,421,746	12/20/1983	Kojima et al.	
		US-4,456,597	06/26/1984	Kojima et al.	
		US-4,469,685	09/04/1984	Kojima et al.	
		US-5,882,672	03/16/1999	Kojima et al.	
		US-			

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[6]

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
		BAERT, F.J. et al., "Tumor Necrosis Factor α-antibody (Infliximab) Therapy Profoundly Down-Regulates the Inflammation in Crohn's Disease," GASTROENTEROLOGY (1999) Vol. 116, pp. 22-28.	
		EHRENPREIS, E.D. et al., "Thalidomide Therapy for Patients with Refractory Crohn's Disease: An Open-Label Trial," Gastroenterology (1997), Vol. 117, pp. 1271-77.	
		THE MERCK MANUAL 16th Edition, p. 1240, 1994.	NO
		MIZOGUCHI, M., "GM-CSF" in CYTOKINE THERAPY: APPROACH FROM BASIS AND PATHEMA, (1993) Nankodo Co., Ltd., Tokyo p. 39-45, ISBN: 4524233628.	NO
		NICOLA, N.A., "GM-CSF" in CYTOKINE REFERENCE A COMPENDIUM OF CYTOKINES AND OTHER MEDIATORS OF HOST DEFENSE, Oppenheim & Feldman, eds., (2001) Academic Press, pp. 899-910.	
		TAKEUCHI, T., "Anti-TNF α Therapy" in SEPARATE VOLUME: PROGRESS OF MEDICAL SCIENCE, IMMUNODEFICIENCY, (2002) Ishiyakushuppan Co., Ltd., pp. 538-42.	NO
		URABE, A., "Blood Disease and Cytokine Therapy, Cytokine Therapy Approach from Start and Pathema," (1993) Nankodo Co., Ltd., Tokyo, pP. 184-94.	NO
		WATANABE, N., "Development of Highly Sensitive Assay for Detection of Intravital Trace Materials and Its Clinical Application," Lab. Clin. Pract. (2002), Vol. 20(2), pp. 110-14.	NO
		YAMAMURA, M., "Clinical Analysis and Treatment of Anemia in Patients of Rheumatoid Arthritis," Report for 6th Incentive Award of the Society of Certifying Specialist in Internal Medicine, 1998.	NO

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.